



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,492	03/24/2006	Michal Eisenbach-Schwartz	EIS-SCHWARTZ26A	1098
1444 7590 05/28/2008 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER DUTT, ADITI	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 05/28/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,492	EISENBACH-SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 30-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 and 30-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to an eye-drop vaccine for therapeutic immunization of a mammal.

Group II, claim(s) 30-43, drawn to a method of therapeutic immunization for treating neuronal degeneration.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

3. A further restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The applicant is required to elect *one* sequence for prosecution, from one of the following groups (A-AF) corresponding to SEQ ID NOs: 1-32 listed in Table 1 on page 12 of the instant specification.

4. The inventions listed as Groups A-AF do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant case, the different inventions of Groups (A-AF) are unique peptide molecules, composed of different amino acids. Accordingly, each of the different protein sequences are not so linked under PCT Rule 13.1 and are thus placed in thirty-two different inventive groups numbered A-AF. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. Furthermore, each of the sequences represents a different peptide with unique and diverse functional features.

Note: This is a Restriction requirement, not an Election of species. In order to be fully responsive, Applicant must select one from Inventions I-II and one from groups A-AF.

5. Species Election

A) Active agent of the vaccine

- a) Copolymer 1
- b) Copolymer 1-related peptide
- c) Copolymer 1-related polypeptide

Art Unit: 1649

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 10-11, 30, 38-39, 43.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above copolymers will comprise distinct peptide sequences, from one another and, therefore, will determine different levels of success. For example, the special technical feature of (a) is Copolymer 1. This special technical feature is not shared by the other species.

B) Causes of neuronal degeneration

- a) Injury
- b) Disease, disorder or condition

The claims are deemed to correspond to the species listed above in the following manner:

Claims 2, 30 and 43.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above causes represents a characteristically different pathology, progression, treatment options and levels of success. For example, the special technical feature of (a) Injury. This special technical feature is not shared by the other species.

C) Action of eye-drop vaccine

- a) Preventing or inhibiting neuronal secondary degeneration
- b) Promoting nerve regeneration
- c) Protecting nerve cells from glutamate toxicity

Art Unit: 1649

The claims are deemed to correspond to the species listed above in the following manner:

Claims 2 and 43

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above actions determine distinct biochemical pathways, different protocols for evaluation and different levels of success, and, therefore, represents a patentably distinct invention. For example, the special technical feature of (a) is Preventing or inhibiting neuronal secondary degeneration. This special technical feature is not shared by the other species.

D) Nervous System

a) Central Nervous System (CNS)

b) Peripheral Nervous System (PNS)

If Applicant elected one species from “Causes of neuronal degeneration” (B), or one species from “Action of eye-drop vaccine” (C), Applicant is further required to select a specific nervous system associated with the “Cause of neuronal degeneration”, or the “Action of eye-drop vaccine” for consideration.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 2, 30 and 43.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above tissues are physiologically different, comprising structurally and functionally different neurons and other cell types from one another and, therefore, represents a patentably distinct invention. For example, the special technical feature of (a) is CNS. This special technical feature is not shared by the other species.

Art Unit: 1649

E) Injury

The species are listed in claims 3 and 31.

The following claim(s) are generic: 2 and 30

If Applicant elected “injury” as the species from “Causes of neuronal degeneration” (B), Applicant is further required to select a specific “injury” for consideration.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above injuries listed in claims 3 and 31 will involve characteristically different trauma, and pathology, requiring different treatment strategies, from one another and, therefore, will determine different levels of success. For example, the special technical feature of Spinal cord injury is not shared by the other species.

F) Disease, disorder or condition

The species are listed in claims 4, 5, 12-14, 32, 33, 40-42.

The following claim(s) are generic: 2 and 30

If Applicant elected “Disease, disorder or condition” as the species from “Causes of neuronal degeneration” (B), Applicant is further required to select a specific “Disease, disorder or condition” for consideration.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above diseases will involve characteristically different etiology, and pathology, requiring different treatment strategies, from one another and, therefore, will determine different levels of success. For example, the special technical feature of Alzheimer’s Disease is not shared by the other species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. In response to this Office Action/Election requirement, applicant must elect one from Groups I-II and (A-AF), and must additionally elect a species of active agent of the vaccine, causes of neuronal degeneration, action of eye-drop vaccine, nervous system, injury and disease, disorder or condition, for consideration.

7. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

Notice of Rejoinder

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Contact Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD
11 May 2008

/Jeffrey Stucker/
Supervisory Patent Examiner, Art Unit 1649